

REMARKS

Claims 1-9 and 11-18 stand rejected. Applicant has amended Claims 1, 11, and 16-18. Applicant has added new Claims 19 and 20, which are supported at least by paragraphs [0044] and [0061]. No new matter has been added. Thus, Claims 1-9 and 11-18 are presented for reconsideration and further examination.

Rejection under 35 U.S.C. §112, ¶ 2

The Examiner rejected Claims 1-4 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the shaft is "without a core shaft and essentially without a continuous core region." Claim 2, which depends on Claim 1, recites that "the shaft has a thin continuous core region having a diameter between 3 mm and almost zero." The Examiner has argued that these two limitations "contradict each other." In the Advisory Action, the Examiner questioned, "How can the instant invention be without a continuous core region and then have a thin continuous core region?" Applicant respectfully disagrees that the limitations contradict and presents clarifying statements below.

The terms "core shaft" and "continuous core region" are described in the specification as two distinct concepts. In particular, paragraph [0019] recites that there is "no continuous core shaft provided, to which the cam discs are attached." The embodiment illustrated in Figures 1 and 2 is "without a core shaft, that is to say no continuous core shaft is provided, to which the cam discs are attached" (paragraph [0044]). In contrast, paragraph [0046] recites "a core region 22 may be continuous, that is to say all the cam segments run through the latter." Figures 13 through 16 illustrate embodiments of shafts with and without a continuous core region as viewed along a central axis. In Figure 13, "a continuous core region 22 is provided" (paragraph [0058]), whereas in Figure 14, "a core region of about zero is provided." Figures 15 and 16 illustrate embodiments without a core region.

When a core shaft is used, as in the prior art, it is generally stable enough to provide a rigid support surface for supporting cam discs. The cams are pushed onto the core shaft and fixed there by means of the shape of the provided core shaft, e.g. as a hexagonal surface. In contrast, the continuous core region of the present invention is not identical with a core shaft, as

embodiments of the present invention are provided as a "one-piece shaft comprising a single homogenous piece of material" wherein "the shaft [has] integral cam segments offset with respect to one another."

When looking in the direction of a central axis (numbered 21 in Figure 2), the area or region all cam segments are going through is denoted the "continuous core region" (numbered 22 in Figures 2B-2E). In certain embodiments, such as those illustrated in Figures 15 and 16, there is *no* continuous core region. With such a shaft, a very high lamella stroke is possible as compared to the prior art shafts having a core shaft and cams mounted thereon.

The small continuous core region of certain embodiments can measure about 2-3 mm and the shaft of certain embodiments can have a length of about 3 cm and a diameter of about 1 cm as measured between the outermost points of the cam segments offset one to another. Such a small shaft can withstand enormous mechanical forces during its use in a pumping apparatus with a peristaltic drive device for pumping a medium through a hose, where the pumping apparatus for medical use can be an infusion pump, a transfusion pump, or a hose pump for medical use. In contrast, Applicant respectfully submits that it would not be possible to provide a very small *core shaft* having a diameter of 2-3 mm and cams or cam segments mounted thereon that can withstand such enormous mechanical forces, as such a small *core shaft* having a diameter of 2-3 mm is not stable enough to withstand these forces. Further, such a shaft having a *core shaft* does not provide a large supporting surface to be able to fix cams or cam segments thereon. Any cams or cam segments fixed on such a small core shaft will not maintain their position on the supporting surface of the core shaft, but rather will move about the shaft, which will lead to problems during the operation of the pumping apparatus.

Camshaft as used in automobiles and other internal combustion engines are very large as compared to the embodiments of the present invention for use in a medical apparatus. It would not be possible to shrink an automobile camshaft since such a shaft would not be able to withstand the mechanical forces acting on the shaft during use in a pumping apparatus for medical use. In particular, the shaft would be unable to withstand the shearing forces during use. Further, such camshafts generally have a large *continuous core region* such that the lamella stroke provided by the shafts is decidedly lower as compared to the lamella stroke provided with

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the shaft in embodiments of the present invention having a thin *continuous core region*, as claimed in Claims 2.

Claim 1 recites that the shaft is “*essentially without* a continuous core region,” whereas Claim 2 recites that the shaft “has a *thin continuous core region* having a diameter between 3 mm and almost zero.” Applicant respectfully submits that these two limitations do not contradict as “essentially without” is not equivalent to “entirely without.”

“The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). MPEP at § 2173.05(b). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.” The same section further gives the example, “The phrase ‘a silicon dioxide source that is *essentially free* of alkali metal’ was held to be *definite* because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (CCPA 1983).” Applicant submits that the specification, at least at paragraph [0019], gives guidelines and examples to enable a person of ordinary skill in the art to understand what is claimed.

Rejection under §35 U.S.C. §103(a) over Magnus in view of Itabashi or Nakamura or Smith

The Examiner rejected Claims 1, 3-9, 11-13, and 15-18 as being unpatentable over Magnus (USPN 5,558,507) in view of Itabashi et al (USPN 5,676,192) or Nakamura et al (USPN 5,778,530) or Smith et al (USPN 6,289,764). In order to provide a *prima facie* showing of obviousness under 35 U.S.C. § 103, all the claim limitations must be taught or suggested by the prior art. *See, e.g., In re Royka*, 490 F.2d 981, 180 USPQ. 580 (CCPA 1974).

Claim 1 is directed to a pumping apparatus that includes, for example, “a one-piece shaft comprising a single homogenous piece of material with integral cams.” Independent Claims 5, 11, and 16-18 recite, for example, a “shaft comprising a single homogenous piece of material.” As noted by the Examiner on page 4 of the Office Action, Magnus fails to disclose, teach, or suggest this feature. The Examiner further states that Smith, Nakamura, and Itabashi all teach

integrally cast cam shafts made of homogenous pieces of material. The Examiner further states that it would be obvious to have made the shaft cams of Magnus from one-piece as taught by Smith, Nakamura, and Itabashi as a design choice, and since it has been held that making in one-piece which has formerly been multiple pieces is a matter of obvious engineering choice. Applicant respectfully disagrees for the reasons set forth below.

Applicant respectfully submits that, as stated in the MPEP at § 2143.01.V, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." Further, as stated in MPEP at § 2145.X.D(2), "It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)." Also, as stated in the MPEP § 2141.02.VI, a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)."

Magnus recites "The object of the present invention is to simplify the construction of the shaft ... while obtaining a basic concept which is favorable for assembly" (Magnus at c. 1, ll. 31-37). In furthering this concept, Magnus discloses a shaft "made up of stub shafts (8) which project on one size (a) of an eccentric disk (7) and engage in corresponding recesses (9) in the adjacent eccentric disk (7)" (Magnus at c. 1, ll. 37-41). As Magnus specifically discloses that the object of the invention is to obtain a basic concept which is favorable for *assembly*, one of ordinary skill in the art would not be motivated to eliminate assembly entirely by constructing the shaft as a homogenous piece of material.

Magnus also discloses that, as "the formation of the shaft is taken over by the eccentric disks, the final length required in each case is also obtained; *no shafts of different lengths need be kept ready*" (Magnus at c. 1, ll. 45-48). To the contrary, if one were to construct the shaft of Magnus as a single homogenous piece of material, shafts of different lengths *would* need to be kept ready. As Magnus specifically teaches away from one-piece construction, one of ordinary skill in the art would not be motivated to construct the shaft of Magnus as a homogenous piece of material.

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Magnus also discloses that construction from multiple pieces “has the result of facilitating assembly” and “any repair work which may be required is also substantially easier” (Magnus at c. 2, ll. 40-44), as individual damages or defective elements can be removed. In the case of one-piece construction, the entire shaft would need to be replaced.

The teachings of Magnus as a whole are directed to the construction of a shaft from multiple staggered disks. One of ordinary skill in the art would not be motivated to ignore every advantage of multiple staggered disk construction disclosed by Magnus and instead form the shaft disclosed from a single piece of homogenous material.

With respect to the prior art references of Smith, Nakamura, and Itabashi, Applicant notes that Smith discloses “casting a blank comprising a central shaft, concentric journal bearings and eccentric cam lobes” (Smith at c. 1, ll. 60-62) for use in an engine, made from either steel or ductile iron (Smith at c. 2, ll. 46-50). Nakamura discloses “a camshaft made of cast iron containing chilled carbide to sliding surface of a cam lobe portion of the camshaft” (Nakamura at c. 1, ll. 54-56) for use in an engine. Itabashi discloses “a camshaft for an internal combustion engine” which includes a body, journals, shaft portions, a plurality of cams, and “a plurality of crescent-shaped sinters 8 each serving as a *cast-in insert* member which is *deposited* to the base circle-portion 5 of each cam 4” (Itabashi at c. 2, ll. 17-24).

Applicant respectfully submits that the cited camshafts for internal combustion engines are not analogous art with respect to the hose pump disclosed in Magnus. In the Advisory Action, the Examiner stated that “it has been held that a prior art reference must either be in the field of the applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis of rejection of the claimed invention. See *In Re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).”

In *Oetiker*, the Applicant’s invention was “an improvement in a ‘stepless, earless’ metal clamp, a hose clamp that was generally described in an earlier ‘004 patent of Oetiker, but that differs in the presence of a feature that is described as a preassembly ‘hook’. This ‘hook’ serves both to maintain the preassembly condition of the clamp and to be disengaged automatically when the clamp is tightened.” The Examiner rejected the claims as unpatentable over Oetiker’s ‘004 patent and a certain Lauro ‘004 patent, which “describes a plastic hook and eye fastener for

use in garments, in which 'unitary tabs of sewing needle puncturable plastic material ... are affixable to clothing and the like by sewing'."

The Board affirmed the Examiner's rejection, as it "apparently reasoned that all hooking problems are analogous." The Federal Circuit dismissed this argument, and **reversed** the rejection, stating "It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness."

Applicant respectfully submits that, as in *Oetiker*, where it was established that not "all hooking problems are analogous," not all shafts are analogous. In particular, the cited camshafts for internal combustion engines are not analogous art with respect to the "eccentric shaft W" disclosed in Magnus.

While the fact that camshafts for internal combustion engines are classified in class 123, subclass 90.17 and Magnus is classified in class 417, subclass 474 is "some evidence of 'nonanalogy,'" "the similarities and differences in structure and function of the inventions [] carry far greater weight." *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973)." MPEP at § 2141.01(a). In the instant case, the differences between the *structures* and *functions* also support Applicant's position that automotive camshafts and the structure disclosed in Magnus are not analogous art.

With respect to the structure, the camshafts of Smith, Nakamura, and Itabashi contain cams separated by "journal bearings" (Smith), spacers (Nakamura at Fig. 1, not numbered or named), or "shaft portions" (Itabashi), whereas the shaft of Magnus is composed of a plurality of discs "stacked" so as to form a package of plates" (Magnus at c. 4, ll. 18-21). With respect to the function, as disclosed by Smith, "[t]he usual function of the camshaft is to actuate the intake and exhaust valves at the appropriate time in the engine operation cycle" (Smith at c. 2, ll. 27-29). In contrast, the hose pump of Magnus is designed to "gently press out the amount which has been precisely separated from the remaining supply" (Magnus at c. 1, ll. 15-17).

Applicant thus respectfully submits that a *prima facie* case of obviousness has not been established and requests that the Examiner withdraw the rejection of independent Claims 1, 5,

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11, and 16-18. Dependent Claims 3-4, 6-9, 12-13, and 15 each depend directly or indirectly from one of the above-referenced independent claims, and is patentable for at least the same reasons that support the allowance of the claim from which it depends.

Rejection under §35 U.S.C. §103(a) over Magnus in view of Itabashi or Nakamura or Smith in further view of Goi

The Examiner rejected Claims 1-2 and 5-9 as being unpatentable over Magnus in view of Itabashi or Nakamura or Smith in further view of Goi et al (DE 69201966). As Goi was introduced for the suggestion of “a continuous core region,” and does not comprise a “single homogenous piece of material,” Applicant respectfully submits that independent Claims 1 and 5 are in condition for allowance for the reasons set forth above. Dependent Claims 2 and 6-9 each depend directly or indirectly from one of the above-referenced independent claims, and is patentable for at least the same reasons that support the allowance of the claim from which it depends.

Claim 2 further recites “the shaft has a thin continuous core region having a diameter between 3 mm and almost zero.” Examiner has argued that that it would have been obvious to make the core shaft of Goi between 3 mm and almost zero since the claimed values are merely an optimum or workable range. Applicant respectfully submits that, as differentiated above with respect to the rejection under 35 U.S.C. § 112, second paragraph, the claim recites a “continuous core region” not a “core shaft” as disclosed in Goi. Further, Applicant submits that a *prima case* of obviousness with respect to ranges applies only “where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’” (see MPEP § 2144.05.I). Also, Applicant submits that, as stated in the MPEP at § 2144.05.II.B, “[a] particular parameter must first be recognized as a result-effective variable, i.e. a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).” None of the cited prior art references refer to the size of a continuous core region as being a result-effective variable, as *is* discussed in the present specification.

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The cited prior art references containing a continuous core region, namely Itabashi, Nakamura, and Smith, are all directed to automobile cam shafts. The MPEP gives further guidance regarding the claims directed to the size of an object at § 2144.04.IV.A, where it states that “In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions *would not perform differently than the prior art device*, the claimed device was not patentably distinct from the prior art device.” In the present application, as discussed above with respect to the rejection under 35 U.S.C. § 112, second paragraph, the claimed device *would* perform differently than the prior art device, as an automobile camshaft of the relative dimensions cited would be unable to withstand the shearing forces and would be inoperable.

Rejection under §35 U.S.C. §103(a) over Magnus in view of Itabashi or Nakamura or Smith in further view of Romanelli

The Examiner rejected Claim 14 as being unpatentable over Magnus in view of Itabashi or Nakamura or Smith in further view of Romanelli et al (USPN 4,755,168). In view of the patentability of Claim 11 from which Claim 14 depends, as discussed above, Applicant respectfully submits that Claim 14 is in condition for allowance.

Discussion of New Claims

Claim 19 depends on Claim 1, which is allowable for the reasons set forth above. In view of the patentability of its base claim, and in further view of its additional technical features, Applicant respectfully submits that Claim 19 is patentable over the prior art of record.

Claim 20 recites “the shaft has no core region.” Applicant respectfully submits that none of the cited references disclose a shaft having no core region, as explained above with respect to the rejection under 35 U.S.C. § 112, second paragraph. Further, Claim 20 depends on Claim 5, which is allowable for the reasons set forth above. In view of the patentability of its base claim, and in further view of its additional technical features, Applicant respectfully submits that Claim 20 is patentable over the prior art of record.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims, and that those claims are in condition for allowance. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole.

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain of if an issue requires clarification, the Examiner is respectfully requested to call Applicants' attorney in order to resolve any such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.


Respectfully submitted,

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3/16/05

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